December 2006

Science Advisory Board Review of Issues Related to Mixtures of Dioxins/Furans, Polycyclic Aromatic Hydrocarbons & Polychlorinated Biphenyls

Background

The Department has begun a rulemaking process to amend the Model Toxics Control Act (MTCA) Cleanup Regulation (Chapter 173-340 WAC). This rulemaking will clarify the policies and procedures for establishing cleanup levels for mixtures of polychlorinated dibenzop-dioxins/ polychlorinated dibenzofurans (dioxins and furans), polycyclic aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs).

Revised Questions and Preliminary SAB Responses

The Department identified a series of questions for the Board's review prior to the September 15th Board meeting. Based on the Board's review, Ecology reorganized and modified the list of questions. The Board discussed the modified list of questions at the October 23rd Board meeting. The revised questions and the status of the Board's review are summarized below.

Mechanism of Action/Mode of Action

Ecology is planning to modify the MTCA rule to clarify that certain types of mixtures (e.g. dioxins/furans, PAHs, etc.) should be treated as a single hazardous substance when establishing cleanup levels and remediation levels. One of the foundations for this policy decision is the conclusion that individual members of different chemical families act through a common biological mechanism of action.

• <u>Dioxins/Furans</u>: Is the conclusion that dioxin and furan congeners act through a common mechanism of action consistent with current scientific information?

<u>SAB's Response</u>: The Board stated that it is reasonable to conclude that the 17 dioxin and furan congeners with chlorine atoms in the 2,3,7 & 8 positions act through a common biological mechanism of action (i.e. binding to the Ah receptor) (NAS, 2006; Van den Berg, et al. 2006; EPA, 2003). The Board noted that it was fortuitous that the EPA, the NAS and the WHO had recently completed reports that support this conclusion.

• <u>Carcinogenic PAHs</u>: Is the conclusion that carcinogenic PAHs act through a common mechanism of action consistent with current scientific information?

<u>SAB's Response</u>: The Board stated that it is reasonable to conclude that carcinogenic PAHs act through a common biological mechanism of action (California EPA, 2005; EPA, 1993; NTP, 2005).

• <u>Dioxin-Like PCBs</u>: Is the conclusion that dioxin-like PCBs act through a common mechanism of action consistent with current scientific information?

<u>SAB's Response</u>: The Board stated that it is reasonable to conclude that coplanar PCBs act through a common biological mechanism of action (i.e. binding to the Ah receptor) (NAS, 2006; Van den Berg, et al. 2006; EPA, 2003). The Board stated that it was fortuitous that the EPA, the NAS and the WHO had recently completed reports that support this conclusion.

• Other Chemical Groups: Are there other chemical groups where current scientific information supports a conclusion that individual members of the group act through a common mechanism?

<u>SAB's Response</u>: The Board concluded that there are several other chemical groups where individual members of the group appear to act through a common mode of action. For example, the Board noted that organophosphate pesticides are known to act on the nervous system through a common mode of action. However, the Board concluded that available scientific information does not support using a TEF approach for other compounds identified by Ecology. In the future, the Board suggested that Ecology may want to consider subclasses for some of the compound groups.

Toxic Equivalency Factors

Ecology is planning to use the Toxicity Equivalency Factors recommended by the World Health Organization (Van den Berg et al. 2006) when establishing and evaluating compliance with cleanup levels and remediation levels for dioxin and furan mixtures and dioxin-like PCBs.

- <u>TEFs for Dioxins/Furans</u>: Are the TEF values recommended by the World Health Organization (WHO) for dioxins and furans consistent with current scientific information?
 - <u>SAB's Response</u>: The Board stated that the TEF values for dioxin and furans recommended by the WHO are consistent with current scientific information. As noted above, the Board stated that it was fortuitous that the WHO had recently completed a review and evaluation of available scientific information which resulted in updated TEF values for dioxins and furans.
- <u>TEFs for Dioxin-Like PCBs</u>: Are the TEF values recommended by the World Health Organization for dioxin-like PCBs consistent with current scientific information?
 - <u>SAB's Response</u>: The Board stated that the TEF values for dioxin-like PCBs recommended by the WHO are consistent with current scientific information. As noted above, the Board stated that it was fortuitous that the WHO had recently completed a review and evaluation of available scientific information which resulted in updated TEF values for dioxins and furans.
- <u>TEFs for Other Hazardous Substances</u>: Is there sufficient scientific information currently available to establish toxic equivalency factors for other groups of hazardous substances?
 - <u>SAB's Response</u>: As noted above, the Board noted that other chemical groups may share a common mechanism of action or mode of action. However, the Board concluded that (with one possible exception) available scientific information does not support using a TEF approach for other chemical groups at this time. The one exception is organophosphate pesticides. It was noted that this is not a major issue when establishing cleanup levels based on non-cancer effect. Specifically, the MTCA rule states that cleanup levels for individual substances (based on a hazard quotient of 1) must be adjusted downward to take into account concurrent exposures to multiple substances that act upon the same organ.

Potency Equivalency Factors

Ecology is planning to use the Potency Equivalency Factors (PEFs) recommended by the California Environmental Protection Agency (Cal EPA, 2005) when establishing and evaluating

compliance with cleanup levels and remediation levels for carcinogenic PAH mixtures. This would be an update of the Cal EPA factors previously addressed in a Board recommendation.

• <u>PEFs for Carcinogenic PAHs</u>: Are the PEF values recommended by the California Environmental Protection Agency consistent with current scientific information?

SAB's Response: The Board stated that the PEF values for carcinogenic PAHs recommended by the California Environmental Protection Agency are consistent with current scientific information. As with dioxins and furans, the Board stated that it was fortuitous that the California EPA had recently completed a review and evaluation of available scientific information and published updated PEF values for carcinogenic PAHs. The Board noted that CalEPA considered a wide range of studies when establishing PEF values. The Board also observed that the California document describing the methodology provides information that is useful for Ecology as it proceeds with the MTCA rule update.

Relative Bioavailability of Dioxin and Furans in Soil

The MTCA Cleanup Regulation establishes methods for calculating soil cleanup levels based on direct contact with contaminated soils. The methods include default assumptions for gastrointestinal absorption fraction, default assumptions for dermal absorption fraction and provisions for modifying the default assumptions on a site-specific basis. In the current MTCA rule, the default assumptions for dioxin/furan mixtures are: (1) 100% of soil-bound dioxins and furans are absorbed into the body when soil is ingested; and (2) 1% of soil-bound dioxin and furans are absorbed through the skin when soil adheres to hands, arms or other parts of the body.

• <u>Default Gastrointestinal Absorption Fraction for Soil-Bound Dioxin/Furan Mixtures</u>: Ecology is considering establishing a default gastrointestinal absorption factor for dioxin/furan mixtures equal to 0.4. Is this default value consistent with current scientific information?

<u>SAB's Response</u>: The Board reviewed this question and reached several conclusions:

- Based on available scientific information, it is reasonable to conclude that soil-bound dioxins and furans are less bioavailable that dioxins and furans in foods and drinking water.
- It is important to consider the absorption of dioxins and furans in soils relative to the amount of absorption in the toxicological studies that were used to establish the cancer slope factors and reference doses.
- Based on available scientific information, it is reasonable to assume that test animals absorbed 80% of the administered dose in the toxicological study used to establish the cancer slope factor for dioxins and furans.

However, the Board did not reach a conclusion on whether it was reasonable to use a 30% absorption value for soil-bound dioxins and furans. They requested that Ecology provided additional information on the designs of key studies (e.g. soil types, test methods, etc.), the range of soil types at Washington cleanup sites and the range of factors that might influence inter- or intra-individual variability in absorption rates.

• <u>Default Dermal Absorption Fraction for Soil-Bound Dioxin/Furan Mixtures:</u> Ecology is considering establishing a default dermal absorption factor dioxin/furan mixtures equal to 0.03. Is this value consistent with current scientific information?

<u>SAB's Response</u>: The Board concluded that using a default dermal absorption value was consistent with current scientific information and regulatory guidance (NRC, 2003; EPA 2003).

Risk Characterization and Regulatory Implementation Issues

• Application to Soil and other Abiotic Media: Ecology is planning to continue to use the TEF and PEF values when establishing and evaluating compliance with cleanup levels and remediation levels for abiotic media (e.g. soil). Is this approach consistent with current scientific information?

<u>SAB's Response</u>: The Board concluded that it was appropriate to continue to use the TEF and PEF values when establishing and evaluating compliance with soil cleanup levels provided that Ecology considered relative bioavailability of soil-bound contaminants (relative to bioavailability in relevant toxicological studies). The Board noted that this is consistent with the report and recommendations prepared by the World Health Organization (Van den Berg, et. al. 2006).

• <u>Cross-Media Transfer – Dioxin/Furans</u>: Ecology is planning to require that cleanup proponents use congener-specific information when evaluating cross-media transfer (e.g. soil to ground water) of mixtures of dioxins, furans and/or polychlorinated biphenyls. Is this approach consistent with current scientific information?

SAB's Response: See response to dioxins and furans.

• <u>Cross-Media Transfer – Carcinogenic PAHs</u>: Ecology is planning to require that cleanup proponents use PAH-specific information when evaluating the cross-media transfer (e.g. soil to ground water) of carcinogenic PAH mixtures. Is this approach consistent with current scientific information?

SAB's Response: See response to dioxins and furans.

References

California Environmental Protection Agency (Cal EPA). 2005. Air Toxics Hot Spots Program Risk Assessment Guidelines, Part II Technical Support Document for Describing Available Cancer Potency Factors. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. May 2005. Pages B-77 to B-97; table adapted from page B-86

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National Research Council (NRC). 2003. Bioavailability of Contaminants in Soils and Sediments: Processes, Tools, and Approaches. National Academy Press. Washington DC.

National Toxicology Program (NTP). 2005. 11th Report on Carcinogens. Department of Health and Human Services, Public Health Service, National Toxicology Program.

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